

510K: 093517

1. Information

- Submitter's

Name: Summit Glove Inc.
Address: 310 South Grant Street
Minerva, Ohio 44657
Phone: 330-868-0066
Contact Person: James Moore
E-mail: jmoore@summitglove.com

2. Name of Device

Trade or Proprietary Name: Nitr iTech®, Non-Sterile Powder-Free Nitrile Examination Glove in the color blue

Common or Usual Name: Synthetic Rubber Examination Gloves

Classification Name: Patient Examination Glove, Powder-Free

- 3. Predicate Device:** Non-Sterile Nitrile Powder-Free Medical Examination Gloves Submission Number: K090828. Based on the below test results, it is concluded the subject gloves are a substantial equivalent to the predicate device.

4. Identification of the Legally Marketed Devices

Powder-Free Nitrile Examination Gloves as described in this 510K Notification is substantially equivalent to the Class 1 patient examination glove bearing the product code 80LZA (21CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D6319-00a, Standard for Nitrile Gloves for Medical Application.

5. Description of Device

Powder-Free Nitrile Medical Examination Gloves meets the current specifications listed under the ASTM Specification D6319-00a, Standard Specification for Nitrile Examination Gloves for Medical Application.

6. Intended Use of Gloves

This is a disposable device intended for medical purposes: that is worn on the examiner hand, to prevent contamination between the patient and examiner.

7. Summary of Performance Data:

Performance data of gloves based on ASTM D6319-00a. ASTM D6319-00a Section 9 is inapplicable for non-sterile examination grade nitrile gloves.

Test	ASTM 6319-00a	Powder-Free Nitrile Examination Gloves
1. Detection of Holes (ASTM 5151)	Multiple Normal G1 AQL = 2.5	Pass G1 AQL = 2.5*
2. Length (mm) Size XS S M L XL	Min 220 - Min 220 - Min 230 - Min 230 - Min 230	240 mm minimum for all sizes*
3. Palm Width (mm) Size XS S M L XL	70 \pm 10 80 \pm 10 95 \pm 10 111 \pm 10 120 \pm 10	73-78 83-88 93-98 103-107 110 – 118*
4. Thickness (mm) Finger Palm	 Min 0.05 Min 0.05	 Min 0.06 Min 0.05*
5. Physical Properties Before Aging Tensile Strength (Mpa) Ultimate Elongation (%) After Aging Tensile Strength (Mpa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 15 – 21 550 – 630* 14 – 22 520 – 610*
6. Powder Content	Max 2.0mg/glove	Below 2.0mg/glove

*Third Party test data is available in Appendix A

The performance data of the gloves as shown above meet the ASTM D6319-00a Standard using the following test methods:

- ASTM D412 Tensile Properties Unaged Test Method A
- ASTM D573 Tensile Properties Aged
- ASTM D5151 Detection of Holes
- ASTM D6124-06 Section 7 Procedure I for Powder-free Gloves

8. The Biocompatibility Test consists of Primary Skin Irritation (CPSC Title 16 Chapter II Part 1500) and Dermal Sensitization Tests (ISO 10993-10).

7. Primary Skin Irritation CPSC Title 16 Chapter II Part 1500	PII Greater or equal to 5.0 indicates an irritate	PII was "0.04"*
8. Dermal Sensitization Test ISO 10993-10	Score greater or equal to 1 indicates irritation/hypersensitivity	Score was "0"*

*Third Party test data is available in Amendment F

The conclusion of the Biocompatibility Testing would indicate that there is no irritation or hypersensitivity to the subject gloves (NitriTech® Non-Sterile Powder-Free Nitrile Examination Gloves in the color blue).

9. Conclusion:

It is concluded that the NitriTech® Non-Sterile Powder-Free Nitrile Examination Gloves in the color blue for this submission meets ASTM D6319-00a, CPSC Title 16 Chapter II Part 1500 and ISO 10993-10 requirements.

Statement concerning the Biocompatibility Testing

The gloves tested in the Biocompatibility Testing were the subject glove (NitriTech®, Non-Sterile Powdered Nitrile Examination Gloves in the color blue) of this submission. Mediamal Testing and Consultancy Services had the Primary Skin Irritation (study report # MB-PSI-27-09) and Dermal Sensitization Test (study report # MB-DSAb-27-09) completed to CPSC Title 16 Chapter II Part 1500 and ISO 10993-10 standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2010

Mr. James Moore
Project Coordinator
Summit Glove, Incorporated
310 South Grant Street
Minerva, Ohio 44657

Re: K093517

Trade/Device Name: NitrTech® Non-Sterile Powdered Nitrile Medical Examination
Gloves in the color blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 10, 2010
Received: June 15, 2010

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to



<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093517

Device Name: Nitr iTech® Non-Sterile Powder Free Nitrile Medical Examination Gloves in the color blue.


Indications For Use:

The nitrile examination gloves are a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between the patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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